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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,811	08/27/1999	PEGGY LEMAUX	18941000710U	8311

20350 7590 06/03/2002  
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SAN FRANCISCO, CA 94111-3834

EXAMINER
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COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/384,811

Applicant(s)

LEMAUX ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

The Amendment filed March 7, 2002, paper no.11, has been entered.

Claims 1-16 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 11, is attached to the instant Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-8 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office actions mailed December 18, 2000 and September 6, 2001.

Applicant's arguments filed March 7, 2002, have been fully considered but they are not persuasive.

Applicant argues that the integrated Ds or Ac element itself is a physical and structural hallmark of the claimed barley plants, and that the plant can be identified based on this hallmark regardless of where in the genome the element is integrated, and regardless of the specific phenotype of the plant.

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The Examiner maintains that since the structure of the Ds or Ac element doesn't relate to a specific functional characteristic, the physical features of the claimed plants cannot be determined.

***Claim Rejections - 35 USC § 103***

Claims 1-14 remain rejected, under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al. and Bancroft et al., for the reasons of record set forth in the office actions mailed December 18, 2000 and September 6, 2001.

Claims 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al., in view of Bancroft et al., and further in view of Perera et al., for the reasons of record set forth in the office actions mailed December 18, 2000 and September 6, 2001.

Applicant's arguments filed March 7, 2002, have been fully considered but they are not persuasive.

Applicant argues that prior to the instant invention, it could not be determined with a reasonable expectation of success that the Ac/Ds system could be used to regenerate stable barley transformants. (reply page 2). Applicant points out that Ac transposase must be expressed at levels sufficient to transactivate Ds, but the level of expression is known to be highly variable in different plant species. Additionally, Applicant points out that the copy number of Ac and/or Ds can also affect transposition frequency. Applicant argues that the variability of transposition frequency in different plant species means that the ability to use the system to generate stable transformants is also variable. Applicant argues that the rejection does not point to any teaching

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or principle in the prior art that would indicate that one skilled in the art would expect that the Ac/Ds system could be used to generate stable barley transformants (reply page 3).

The Examiner observes that claims 1-16 still do not recite any specific limitations that clearly teach over the prior art of McElroy et al., Wan et al., Bancroft et al., and Perera et al. The claims still do not elucidate what Applicant did differently from McElroy et al., Wan et al., and Bancroft et al. The Examiner still maintains that the success of Wan et al. in transforming barley, and the success of McElroy et al. in demonstrating Ac transposase-mediated excision of Ds in barley cells, would motivate one of skill in the art to combine the teachings of the teachings with a reasonable expectation of success. The Examiner still maintains that the success of Bancroft et al. in using the Ac and Ds transposable elements in another heterologous plant transformation system would provide further motivation to combine the teachings. Additionally, while the level of Ac transposase expression varies in different species and may affect Ds transactivation, and while the copy number of Ac and/or Ds may also affect Ds transposition frequency, the Examiner maintains that the teaching of McElroy et al. demonstrating Ac transposase-mediated excision of Ds in barley cells would indicate that one skilled in the art would expect that the Ac/Ds system could be used to generate stable barley transformants.

### ***Claim Rejections - 35 USC § 101***

Claims 1-8 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility, for the reasons of record set forth in the office action mailed September 6, 2001.

Claims 1-8 also remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the office action mailed September 6, 2001. Specifically, since the claimed

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invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed March 7, 2002, have been fully considered but they are not persuasive.

Applicant argues that the application discloses utilities for barley plants generated using the Ac/Ds system, and that such utilities would be readily apparent to one skilled in the art. Applicant points to specific examples on page 4 of the specification, namely using the claimed plants for the expression of a beneficial transgene absent selectable or screenable marker genes, and using the claimed plants as source material for the isolation of transposon tag genes. Applicant asserts that the disclosed utilities are substantial because they are real world uses, and are credible because they are believable to one skilled in the art (reply page 4). Applicant also argues that because the application meets the utility requirements, the rejection under 35 U.S.C. 112, first paragraph should be withdrawn (reply page 5).

The Examiner maintains that the disclosed utilities are not specific, because utilities such as using the claimed plants for the expression of a beneficial transgene absent selectable or screenable marker genes, or using the claimed plants as source material for the isolation of transposon tag genes, are utilities that are generally applicable to any plant comprising any transposable element system, and are not utilities particular to the products claimed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
May 30, 2002

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800

*EJM*